FEB 7 2013

510(k) Summary	
510(k) Number	K122587
Submitter Information:	
Date Prepared:	August 16, 2012
Submitter Name & Address:	St. Jude Medical - Atrial Fibrillation Division 14901 DeVeau Place Minnetonka, MN 55345 Establishment Registration Number: 3005188751
Contact Person:	Harlan Jones Senior Regulatory Affairs Specialist Phone (651) 756-3429 Fax (651) 756-3298 JonesH02@sjm.com
Device Information:	
Trade Name:	BRK™ Transseptal Needle
Common Name:	Transseptal Needle
Classification Name:	Trocar
Class:	Class II, 21 CFR 870.1390, Product Code DRC
Predicate Device:	BRK™ Transseptal Needle (K072278).
Device Description:	The St. Jude Medical BRK™ Transseptal Needle consists of a luminal stainless steel needle and solid stainless steel stylet. The distal section of the needle is curved to facilitate positioning within the heart when used with a St. Jude Medical Transseptal Introducer set. Within this curved section, there is an abrupt step down in the outer diameter of the needle to mate with the internal diameter of the dilator of the St. Jude Medical Transseptal Introducer set. The distal tip of the needle is beveled to facilitate the puncture process. The proximal end of the needle is configured with a pointer flange (indicating distal curve orientation) and is fitted with a 2-way stopcock to provide needle lumen access for aspiration, fluid injection/infusion, blood sampling, pressure monitoring, and stylet and/or guidewire insertion. The stylet is straight and isodiametric throughout its length. The proximal end of the stylet is fitted with a curved clip to lock onto the proximal needle hub when inserted into the needle lumen. The stylet is designed to facilitate needle advancement within the dilator.
Intended Use: (Indications for Use)	The BRK™ Transseptal Needle is used to puncture the interatrial septum during a transseptal catheterization procedure to gain left heart access.

Comparison to Predicate Devices	The modified BRK™ Transseptal Needle has the same intended use and fundamental scientific technology as the predicate device. The technological characteristics of the modified BRK™ Transseptal Needle are substantially equivalent to the predicate device including packaging, biocompatibility, sterilization, and labeling. Through biocompatibility and design verification testing it was demonstrated that the adhesive change does not adversely affect the safety and effectiveness.
Summary on Non-Clinical Testing	Bench testing and biocompatibility testing were performed to verify the device modification. It was concluded that the modified BRK™ Transseptal Needle design meets the product specification and intended use. Biocompatibility was confirmed in accordance with ISO 10993-1.
Statement of Equivalence	The modified St. Jude Medical BRK™ Transseptal Needle has the same indications for use and technological characteristics as the predicate device. Based on this and the data provided in this pre-market notification, St. Jude Medical's modified BRK™ Transseptal Needle has been shown to be substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

FEB 7 2013

St. Jude Medical
Mr. Harlan Jones
14901 Deveau Pl.
Minnetonka, MN 55345-2126 US

Re: K122587
Trade/Device Name: BRK Transseptal Needle model 407200, 407201, 407205, 407206, 407207, G407208
Regulation Number: 21 CFR 870.1390
Regulation Name: Trocar
Regulatory Class: Class II
Product Code: DRC
Dated: January 10, 2013
Received: January 11, 2013

Dear Mr. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K122587

Device Name: BRK™ Transseptal Needle

Indications for Use:

The BRK™ Transseptal Needle is used to puncture the interatrial septum during a transseptal catheterization procedure to gain left heart access.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K122587